

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2002N-0305]

**Medical Devices: Classification of the Dental Sonography Device and Jaw Tracking Device**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is classifying the dental sonography device into class I, when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA is classifying the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

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Certifier A. Corbin

NFR 1

**DATES:** This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Mary S. Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94-295), the SMDA (Public Law 101-629), and FDAMA (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices as a function of the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking

process. Those devices remain in class III and require premarket approval, unless and until FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) issues, under section 513(i) of the act, an order finding the device as substantially equivalent to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to preamendments devices by means of premarket notification procedures as delineated in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments type device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval. Consistent with the act and the regulations, FDA consulted with the Dental Products Advisory Panel (the Panel), an FDA advisory committee, regarding the classification of the dental sonography device and the jaw tracking device.

## **II. Regulatory History of the Device**

In the **Federal Register** of August 14, 2002 (67 FR 52901), FDA proposed to classify the dental sonography device into class I when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA also proposed to classify the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret

mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain.

FDA provided an opportunity for interested persons to comment on the proposed regulation and guidance document until November 12, 2002. FDA received one comment from a consumer, however, the comment was irrelevant to the proposed rule because it was referring to a different device. A manufacturer commented that the identification of the class II sonography could be read to place a device in class II even if it does not interpret sounds. The comment said that a device is appropriately in class II if it interprets sounds. The comment further suggested that FDA should define “interpret” to mean that the device provides a specific diagnosis and not just meaningful output.

FDA agrees that the identification may not have been clear and has revised § 872.2050(b) by combining the last two sentences to clarify that interpretation is a necessary part of the identification. FDA disagrees that “interpret” should mean that a device provides a specific diagnosis. FDA believes that it is necessary that the manufacturer of a class II dental sonography device that goes beyond a simple display of raw data should provide clinical information and verification that the information provided by these devices has clinical and diagnostic validity, sensitivity, and specificity and, therefore, the special control, in addition to the general controls, is necessary to provide reasonable assurance of safety and effectiveness.

### **III. Summary of Final Rule**

FDA concurs that the dental sonography device and the jaw tracking device, used to monitor temporomandibular joint sounds and mandibular jaw positions relative to the maxilla, respectively, should be classified into class

I (general controls). General controls would provide reasonable assurance of safety and effectiveness for these devices for these intended uses. FDA, however, believes that the dental sonography device and the jaw tracking device used to interpret temporomandibular joint sounds and mandibular jaw positions relative to the maxilla, respectively, for the diagnosis of temporomandibular joint disorders and associated orofacial pain should be classified into class II (special controls). Premarket notification for dental sonography and jaw tracking devices with these intended uses should include clinical information to demonstrate performance, as well as labeling instructing the user on proper technique, interpretation of the device outputs, and appropriate warnings and precautions. FDA concurs with the Panel's recommendation that these devices should be subject to sale by or on the order of a licensed practitioner.

FDA disagrees with the Panel that the class I devices should require premarket notification because they meet the reserved criteria of section 510(l) of the act. FDA believes that the intended uses of monitoring sounds emanated from the temporomandibular joint or monitoring mandibular jaw positions relative to the maxilla should be exempt from premarket notification. FDA believes these devices for these intended uses are not of substantial importance in preventing impairment of human health, nor do they present an unreasonable risk of illness or injury.

FDA, however, is classifying into class II, the dental sonography device and the jaw tracking device used to interpret temporomandibular joint sounds and mandibular jaw positions relative to the maxilla, respectively, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. Section 510(m) of the act provides that a class II device may be exempted from

the premarket notification requirements, if FDA determines that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness. FDA concludes that premarket notification is necessary.

FDA has identified the following risks to health associated with the class II devices as follows: (1) *Electrical interference*. Electrical interference generated by these devices may affect diagnostic and therapeutic medical devices, such as certain types of cardiac pacemakers; (2) *Improper treatment*. There is no general consensus or established standard of care regarding the interpretation of the output of these devices. Therefore, a misdiagnosis of temporomandibular joint disorders and associated orofacial pain may lead to improper treatment.

#### **IV. Special Controls Guidance Document**

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled “Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices.” This guidance document will serve as the special control for the class II dental sonography and jaw tracking devices.

FDA believes that review of performance characteristics described in the special controls guidance and appropriate labeling can ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device must submit to FDA a premarket notification submission before marketing the device. Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for these class II devices will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the

guidance or in some other way provides equivalent assurances of safety and effectiveness.

## **V. Environmental Impact**

The agency has determined under 21 CFR 25.34(b) that this classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## **VI. Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives. If regulation is necessary, a regulatory agency must plot a course that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. Additionally, as defined by the Executive order the final rule does not constitute a significant regulatory action. As a result, the final rule is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The class I devices are already subject to the general controls provisions of the act. The special controls guidance does not impose any new requirements on manufacturers of class I devices. Manufacturers of the class II dental sonography and jaw tracking devices currently are required to submit premarket notifications. The guidance document reflects existing FDA practice

in the review of these premarket notifications. FDA expects that manufacturers of cleared dental sonography and jaw tracking devices will not have to take any additional action in response to this rule. This rule will help expedite the review process for any new manufacturers of these devices. The agency therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## **VII. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## **VIII. Paperwork Reduction Act of 1995**

FDA concludes that the final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, according to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

## **List of Subjects in 21 CFR Part 872**

Medical devices.



■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

## **PART 872—DENTAL DEVICES**

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 872.2050 is added to subpart B to read as follows:

### **§ 872.2050      Dental sonography device.**

(a) *Dental sonography device for monitoring—(1) Identification.* A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.

(2) *Classification.* Class I. The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to § 872.9.

(b) *Dental sonography device for interpretation and diagnosis—(1) Identification.* A dental sonography device for interpretation and diagnosis is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components.

(2) *Classification*. Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices."

■ 3. Section 872.2060 is added to subpart B to read as follows:

**§ 872.2060      Jaw tracking device.**

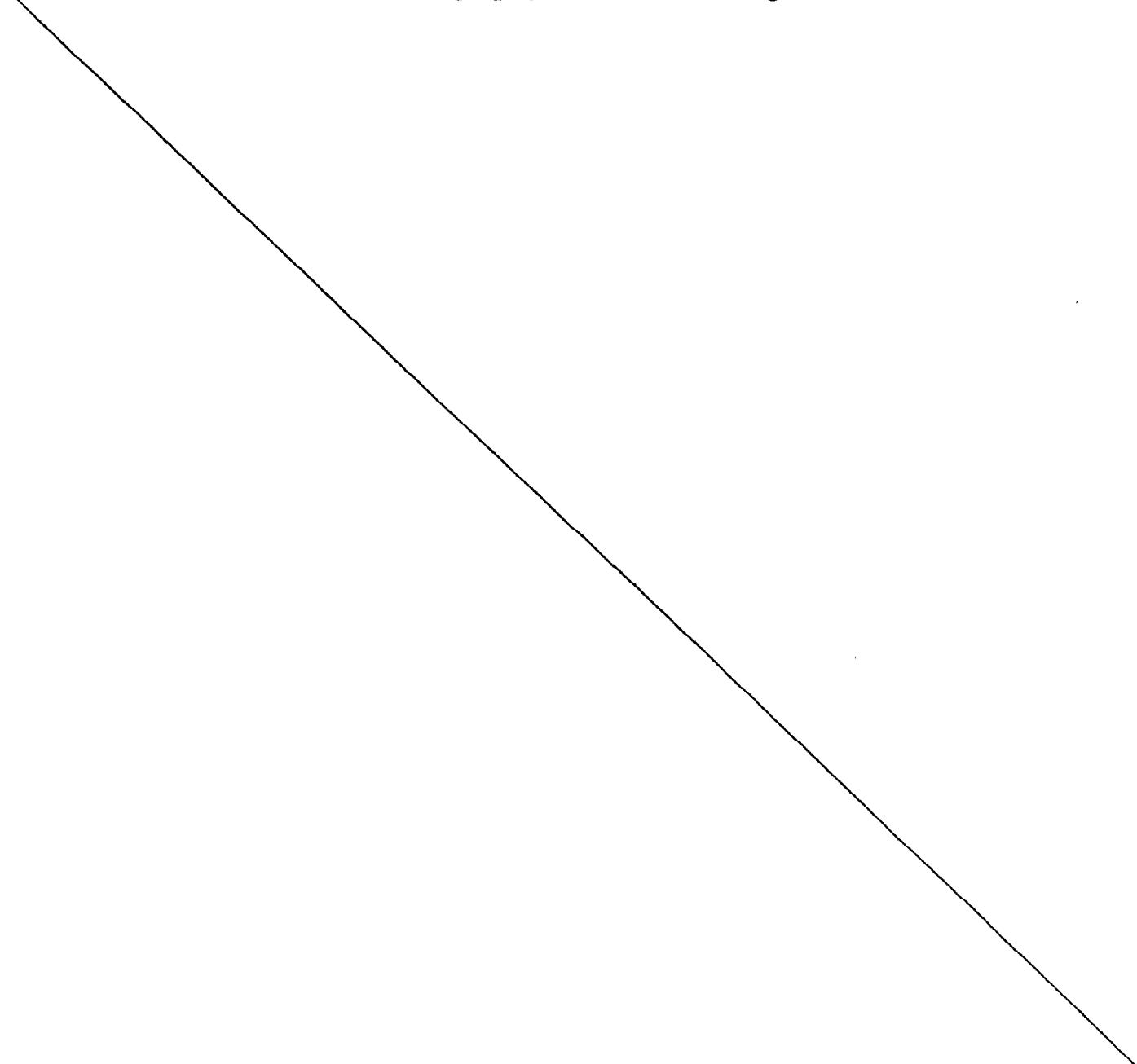
(a) *Jaw tracking device for monitoring mandibular jaw positions relative to the maxilla*—(1) *Identification*. A jaw tracking device for monitoring mandibular jaw positions relative to the maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.

(2) *Classification*. Class I (general controls). The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to § 872.9.

(b) *Jaw tracking device for interpretation of mandibular jaw positions for the diagnosis*—(1) *Identification*. A jaw tracking device for interpretation of mandibular jaw positions relative to the maxilla for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices,

contributing jaw position information to be considered with data from other diagnostic components.

(2) *Classification*. Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices."



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